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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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SMITH & REYNOLDS
175 N. 17th St.
P.O. Box 1000
Greenville, S.C. 29602

EXAMINER

ART UNIT	PAPER NUMBER
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8

DATE MAILED:

07/25/11

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/607,156

Applicant(s)

LOETSCHER ET AL.

Examiner

Joseph F Murphy

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-17, 19-21 and 60-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19-21, 60 and 69-76 is/are allowed.
- 6) ☒ Claim(s) 16, 17, 61-68 and 77-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 16-17 and 61-64 were amended in Paper No. 7, 3/1/2001. Claims 16-17, 19-21 and 60-84 are pending and under consideration.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office Action.

Response to Amendment

The rejection of claims 19-21, 60, 69-76 under 35 USC § 112, first paragraph as lacking enablement for "variants" is withdrawn based on Applicants arguments.

The rejection of claims 16-17, 61-64 under 35 USC § 112, second paragraph for recitation of the term "selectively" has been obviated by Applicant's amendment, and is thus withdrawn.

The rejection of claims 16-17, 19-21 and 60-84 under 35 USC § 102(a) has been withdrawn based upon Applicant's argument that the polypeptide taught in Marchese et al. lacks four amino acids at the N-terminal domain that are disclosed in SEQ ID NO: 2.

Claim Rejections - 35 USC § 112 first paragraph

Claims 16-17, 61-68 and 77-84 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a substantially purified polypeptide comprising an amino acid sequence set forth in SEQ ID NO: 2, does not reasonably provide

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enablement for amino acid sequences that are variants of said sequences for reasons of record set forth in Paper No. 5, 12/15/2001.

Applicant argues that the claims recite functional limitations and that the specification provides sufficient guidance as to the structure/function relationship of the CXCR3 polypeptide. However, as shown by the Mikayama and Voet references cited in Paper No. 5, 12/15/2000 even single amino acid changes can have large and unpredictable effects on the function of the mutein. Based upon the unpredictability of the protein art, as shown by Mikayama and Voet, it would require undue experimentation for one of skill in the art to make and use the claimed invention.

Claims 63-64, 83-84 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a substantially purified polypeptide comprising an amino acid sequence set forth in SEQ ID NO: 2, does not reasonably provide enablement for a variant having at least 90% amino acid sequence identity to SEQ ID NO: 2 for reasons of record set forth in Paper No. 5, 12/15/2001.

Applicant argues that guidance has been provided for methods to determine sequence identity, and that the specification discloses numerous amino acid modifications that do not result in a loss of function. However, as demonstrated in the previous Office Action by the Mikayama et al. and Voet et al. references cited therein demonstrate the unpredictability of the

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protein art as it relates to mutations, even mutations as small as a single amino acid change.

Therefore the rejection is maintained.

Claim 16 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record set forth in Paper No. 5, 12/15/2001.

Applicant argues that the CXCR3 protein is encoded by a double stranded nucleic acid. However, it is the sense strand that encodes the polypeptide, and this could not hybridize to itself.

Claim Rejections - 35 USC § 112 second paragraph

Claim 16-17, 19-21 and 60-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record set forth in Paper No. 5, 12/15/2001.

Claim 16 recites the term "high stringency", which is a conditional term and renders the claim indefinite. Applicant argues that examples of high stringency conditions are provided in the specification, however, although the claims are interpreted in light of the specification.

limitations from the specification are not read into the claims. In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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Claim 16 is vague and indefinite because it is unclear how a nucleic acid could hybridize to both a second nucleic acid, as well as to a sequence complementary to the second nucleic acid. As noted above, it is the sense strand that encodes the polypeptide, and this could not hybridize to itself.

Conclusion

Claims 19-21, 60 and 69-76 are allowable.

Claims 16-17, 61-68 and 77-84 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

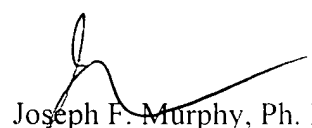
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

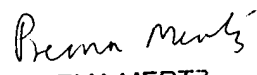
Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
July 24, 2001


PREMA MERTZ
PRIMARY EXAMINER